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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/758,242 Confirmation No. : 5321  
Applicant : Bernd SUNDERMANN, et al.  
Filed : January 16, 2004  
TC/A.U. : 1621  
Examiner : Unassigned  
Docket No. : 029310.53136US  
Customer No. : 23911  
Title : Substituted 4-Aminocyclohexanols

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and/or listed herein and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

**STATEMENT OF RELEVANCE**

The relevance of these references to the subject matter of the present invention is given in the specification of the present invention.

English abstracts are submitted herewith for the references listed on the PTO 1449 as AH-AK.

Applicant encloses herewith a copy of a corresponding International Search Report citing the documents listed on the PTO 1449 as AH-AJ and AL-AM, together with an English-language version (if not already included) of that

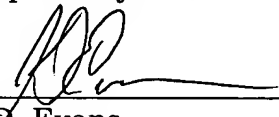
portion of the Search Report indicating the degree of relevance found by the foreign office.

Applicant also encloses herewith a copy of a corresponding German Office Action citing the documents listed on the PTO 1449 as AA-AG and AK, together with an English-language version (if not already included) of that portion of the Search Report indicating the degree of relevance found by the foreign office.

The present Information Disclosure Statement is being filed (1) no later than three months from the application's filing date or (2) before the mailing date of the first Office Action on the merits (whichever is later), and therefore no certification under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

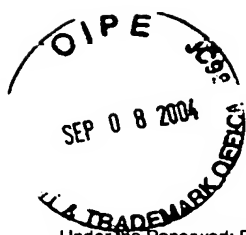
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,

  
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J. D. Evans  
Registration No. 26,269

September 8, 2004

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PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/758,242	
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			First Named Inventor	Bernd SUNDERMANN	
			Art Unit	1621	
			Examiner Name	Unassigned	
Sheet	1	of	5	Attorney Docket Number	029310.53093US

U.S. PATENT DOCUMENTS						
Examiner Initials'	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
	AA	US- 5,304,479		04-19-1994	Cheng-I Lin	
	AB	US- 5,239,110		08-24-1993	John P. Mallamo et al.	
	AC	US- 4,366,172		12-28-1982	Daniel Lednicer	
	AD	US- 4,346,101		08-24-1982	Daniel Lednicer	
	AE	US- 4,212,878		07-15-1980	Daniel Lednicer et al.	
	AF	US- 4,115,589		09-19-1978	Daniel Lednicer	

FOREIGN PATENT DOCUMENTS						
Examiner Initials'	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> —Number <sup>4</sup> —Kind Code <sup>5</sup> (if known)				
	AG	DE 2839891	04-12-1979	The Upjohn Co.		AB
	AH	DE 19963175	07-12-2001	Gruenenthal GmbH		AB
	AI	WO 01/12195	02-22-2001	Gruenenthal GmbH		AB
	AJ	EP 0410191	01-30-1991	Bayer AG		AB

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	AK	DANIEL LEDNICER ET AL., "4-(p-Bromophenyl)-4-(dimethylamino)-1-phenethylcyclohexanol, an Extremely Potent Representative of a New Analgesic Series", Journal of Medicinal Chemistry, October 1979, pp. 1157-1158, Vol. 22, No. 10, American Chemical Society		
	AL	HIROSHI KAWAMOTO ET AL., "Synthesis of J-113397, the First Potent and Selective ORL1 Antagonist," Tetrahedron, 2001, pp. 981-986, 57, Elsevier Science Ltd.		
	AM	PHILLIP F. VONVOIGTLANDER ET AL., "4-Aryl-4-aminocyclohexanones Derivatives: A Chemical Novel Series of Analgesics Including Opioid Antagonist and Extremely Potent Agonist," pp. 17-21		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	5	Attorney Docket Number	029310.53093US

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	AN	FAUD A. ABDULLA ET AL., "Axotomy Reduces the Effect of Analgesic Opioids Yet Increases the Effect of Nociceptin on Dorsal Root Ganglion Neurons," The Journal of Neuroscience, December 1, 1998, pp. 9685-9694, 18, 23, Society for Neuroscience	
	AO	GIROLAMO CALO ET AL., "Pharmacology of Nociceptin and its Receptor: A Novel Therapeutic Target," British Journal of Pharmacology, 2000, pp. 1261-1283, 129, Macmillan Publishers Ltd.	
	AP	MARK CONNER ET AL., "The Effect of Nociceptin on Ca <sup>2+</sup> Channel Current and Intracellular Ca <sup>2+</sup> in the SH-SY5Y Human Neuroblastoma Cell Line", 1996, pp. 205-207, 118, Stockton Press	
	AQ	E.S.L. FABER ET AL., "Depression of Glutamatergic Transmission by Nociceptin in the Neonatal Rat Hemisectioned Spinal Cord Preparation <i>In Vitro</i> ", Special Report, July 19, 1996, pp. 1-2,	
	AR	"Opioid and Opiate Receptors: Peptides and Knock-Out," Society for Neuroscience, 1998, p. 1358, Vol. 24	
	AS	FRANCOIS JENCK ET AL., "Orphanin FQ Acts as an Anxiolytic to Attenuate Behavioral Responses to Stress," Proc. Natl. Acad. Sci., December 1997, pp. 14854-14858, Vol. 94, USA	
	AT	MICHAEL A. KING ET AL., "Spinal Analgesic Activity of Orphanin FQ/Nociceptin and its Fragments", Neuroscience Letters, 1997, pp. 113-116, 223, Elsevier Science Ireland Ltd.	
	AU	TOSHIYA MANABE ET AL., "Facilitation of Long-Term Potentiation and Memory in Mice Lacking Nociceptin Receptors", Letters To Nature, August 6, 1998, pp. 577-581, Vol. 394, Macmillan Publishers Ltd.	
	AV	JEAN-CLAUDE MEUNIER ET AL., "Isolation and Structure of the Endogenous Agonist of Opioid Receptor-Like ORL <sub>1</sub> Receptor," Letters to Nature, October 12, 1995, pp. 532-535, Vol. 377	

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	AW	J.S. MOGIL ET AL., "Orphanin FQ is a Functional Anti-Opioid Peptide", Neuroscience, 1996, pp. 333-337, Vol. 75, No. 2, Elsevier Science Ltd., Great Britain	
	AX	MIYUKI NISHI ET AL., "Unrestrained Nociceptive Response and Disregulation of Hearing Ability in Mice Lacking the Nociceptin/OrphaninFQ Receptor," The EMBO Journal, 1997, pp. 1858-1864, Vol. 16, No. 8, Oxford University Press	
	AY	RAINER K. REINSCHIED ET AL., "Orphanin FQ: A Neuropeptide That Activates an Opioidlike G Protein-Coupled Receptor," Science, November 3, 1995, pp. 792-794, Vol. 270	
	AZ	CHRISTOPHER W. VAUGHAN ET AL., "Increase by the ORL <sub>1</sub> Receptor (Opioid Receptor-like <sub>1</sub> ) Ligand, Nociceptin, of Inwardly Rectifying K Conductance in Dorsal Raphe Nucleus Neurons," Special Report, pp. 1609-1611	
	BA	TATSUO YAMAMOTO ET AL., "Effects of Intrathecally Administered Nociceptin, an Opioid Receptor-like <sub>1</sub> Receptor Agonist, and N-methyl-D-aspartate Receptor Antagonist on the Thermal Hyperalgesia Induced by Partial Sciatic Nerve Injury in the Rat," Anesthesiology, 1997, pp. 1145-1152, Vol. 87, No. 5, Lippincott-Raven Publishers	
	BB	ALI ARDATI ET AL., "Interaction of [ <sup>3</sup> H]Orphanin FQ and [ <sup>125</sup> I]-Tyr <sup>14</sup> -Orphanin FQ with the Orphanin FQ Receptor: Kinetics and Modulation by Cations and Guanine Nucleotides," Molecular Pharmacology, 1997, pp. 816-824, 51, The American Society for Pharmacology and Experimental Therapeutics	
	BC	HUNTER C. CHAMPION ET AL., "[Tyr <sup>1</sup> ]-Nociceptin, a Novel Nociceptin Analog, Decreases Systemic Arterial Pressure by a Naloxone-Insensitive Mechanism in the Rat," Biochemical and Biophysical Research Communications, 1997, pp. 309-312, 234, Academic Press	
	BD	TRISTAN DARLAND ET AL., "Orphanin FQ/nociceptin: a Role in Pain and Analgesia, But So Much More," TINS, 1998, PP. 215-221, Vol. 21, No. 5, Elsevier Science Ltd.	

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	BE	BULENT GUMUSEL ET AL., "Nociceptin: An Endogenous Agonist for Central Opioid Like <sub>1</sub> (ORL <sub>1</sub> ) Receptors Possesses Systemic Vasorelaxant Properties," Life Sciences, 1997, pp. PL 141-145, Vol. 60, No. 8, Elsevier Science Inc., USA	
	BF	NAOKI HARA ET AL., "Characterization of Nociceptin Hyperalgesia and Allodynia in Conscious Mice," British Journal of Pharmacology, 1997, pp. 401-408, 121, Stockton Press	
	BG	DANIEL R. KAPUSTA ET AL., "Diuretic and Antinatriuretic Responses Produced by the Endogenous Opioid-Like Peptide, Nociceptin (Orphanin FQ)," Life Sciences, 1997, pp. PL 15-21, Vol. 60, No. 1, Elsevier Science Inc., USA	
	BH	FREDERIC KNOFLACH ET AL., "Modulation of Voltage-Gated Calcium Channels by Orphanin FQ in Freshly Dissociated Hippocampal Neurons," The Journal of Neuroscience, November 1, 1996, pp. 6657-6664, 16, 21, Society for Neuroscience	
	BI	HANS MATTHES ET AL., "Functional Selectivity of Orphanin FQ for Its Receptor Coexpressed with Potassium Channel Subunits in <i>Xenopus laevis</i> Oocytes," Molecular Pharmacology, 1996, pp. 447-450, 50, The American Society for Pharmacology and Experimental Therapeutics	
	BJ	JEFFREY S. MOGIL ET AL., "Functional Antagonism of $\mu$ -, $\delta$ - and $\kappa$ -opioid Antinociception by Orphanin FQ," Neuroscience Letters, 1996, pp. 131-134, 214, Elsevier Science Ireland Ltd.	
	BK	CATHERINE MOLLEREAU ET AL., "ORL1, A Novel Members of the Opioids Receptor Family Cloning, Functional Expression and Localization," FEBS Letters, 1994, 341, Federation of European Biochemical Societies	
	BL	JAMES D. POMONIS ET AL., "Orphanin FQ, Agonist of Orphan Opioid Receptor ORL <sub>1</sub> , Stimulates Feeding in Rats," NeuroReport, December 20, 1996, pp. 369-371, Vol. 8, No.1, Rapid Science Publishers	

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	BN	XIAO-JUN XU ET AL., "Nociceptin or Antinociceptin: Potent Spinal Antinociceptive Effect of Orphanin FQ/ Nociceptin in the Rat," <i>NeuroReport</i> , September 2 1996, Vol. 17, No. 13, Rapid Science Publishers	
	BO	T. YAMAMOTO ET AL., "Analgesic Effect of Intrathecally Administered Nociceptin, an Opioid Receptor-Like <sub>1</sub> Receptor Agonist, in the Rat Formalin Test," <i>Neuroscience</i> , 1997, pp. 249-254, Vol. 81, Elsevier Science Ltd.	
	BP	M.N.A. RAO ET AL., "Quantitative Correlation Between Hydrophobicity and Analgesis Activity of 4-Amino 4-Arylcyclohexanols," <i>Indian Drugs</i> , 1985, pp. 252-257, 22, 5	
	BQ	JEAN-MARC KAMENKA ET AL., "Orientation Structurale et Conformationnelle de la Fixation de la Phencyclidine dans le SNC," <i>Eur. J. Med. Chem.</i> 1984, pp. 255-260, 19, 3	
	BR	DANIEL LEDNICER ET AL., "4-Amino-4-arylcyclohexanones and Their Derivatives, a Novel Class of Analgesics", <i>J. Med. Chem.</i> , 1980, pp. 424-430, 23	

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